Statement of Deficiencies	**(X1) Provider/Supplier/CLIA Identification Number**	**(X3) Date Survey Completed**
	49D1023017	12/19/2023
Name of Provider or Supplier	**Street Address, City, State**	
Skin & Laser Surgery Center Pc	2200 Opitz Boulevard, Suite 100, Woodbridge, VA	

For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D0000	An announced CLIA recertification survey was conducted at Skin & Laser Surgery Center, PC on December 18-19, 2023 by the Virginia Department of Health's Office of Licensure and Certification. The laboratory was surveyed under 42 CFR part 493 CLIA Regulations. While on-site the laboratory experienced a power outage which delayed and limited the retrieval of documents. Note that the laboratory was not in compliance with the following Conditions: D5400 - 42 CFR 493.1403 Condition: Analytic Systems; D6076 - 42 CFR. 493.1441 Laboratory Director. The specific deficiencies cited are as follows:
D5400	ANALYTIC SYSTEMS CFR(s): 493.1250 Each laboratory that performs nonwaived testing must meet the applicable analytic systems requirements in 493.1251 through 493.1283, unless HHS approves a procedure, specified in Appendix C of the State Operations Manual (CMS Pub.7), that provides equivalent quality testing. The laboratory must monitor and evaluate the overall quality of the analytic systems and correct identified problems as specified in 493.1289 for each specialty and subspecialty of testing performed. This CONDITION is not met as evidenced by: Based on a tour, review of the laboratory's policies and procedures, method validation documents, quality control records, Mohs logs, lack of documentation and interviews, the laboratory failed to: 1. document a written policy for the performance of MART-1 Immunohistochemical (IHC) staining utilizing the BioSB Mohs Mouse/Rabbit PolyDetector HRP Brown Detection System from October 26, 2023 until the date of the survey on December 18, 2023 (see D5401), 2. validate the performance specifications of a laboratory developed test (LDT), MART-1 IHC staining utilizing the BioSB Mohs Mouse/Rabbit PolyDetector HRP Brown Detection System from October 26, 2023 until the date of the survey on December 18, 2023 (see D5423). 3. perform and document the positive and negative reactivity each day of use for MART-

	1 IHC staining utilizing the BioSB Mohs Mouse/Rabbit PolyDetector HRP Brown Detection System (see D5601).
D5401	PROCEDURE MANUAL CFR(s): 493.1251(a) A written procedures manual for all tests, assays, and examinations performed by the laboratory must be available to, and followed by, laboratory personnel. Textbooks may supplement but not replace the laboratory's written procedures for testing or examining specimens. This STANDARD is not met as evidenced by: Based on a tour of the laboratory, review of the laboratory's policy and procedure manual, reagent invoices, lack of documentation and interviews, the laboratory failed to document a written policy for the performance of MART-1 Immunohistochemical (IHC) Staining utilizing the BioSB Mohs Mouse/Rabbit PolyDetector HRP Brown Detection System from October 26, 2023 until the date of the survey on December 18, 2023. The findings include: 1. During a tour of the laboratory on December 18, 2023 at approximately 9:00 AM, the surveyor noted a sheet of paper posted in the Mohs laboratory above the slide stainer with the title, "MART-1 ANTIBODY STAIN CHEAT SHEET". The surveyor inquired of the Mohs Tech how the posted document was utilized. The Mohs Tech stated they used the "CHEAT SHEET" when performing MART-1 staining for suspected Melanoma cases. The surveyor asked the Mohs Tech when they began using the MART-1 stain. The Mohs Tech stated they recently began using the stain but they were not sure of the date. 2. Review of the "MART-1 ANTIBODY STAIN CHEAT SHEET" revealed the steps for performing the MART-1 IHC staining. The document was not signed/dated by the laboratory director. 3. Review of the laboratory's policy and procedure manual revealed the laboratory lacked documentation of a written procedure for the performance of MART-1 IHC staining utilizing the BioSB Mohs Mouse/Rabbit PolyDetector HRP Brown Detection System. The surveyor requested to review the written procedure for MART-1 IHC staining utilizing the BioSB Mohs Mouse/Rabbit PolyDetector HRP Brown Detection System . The laboratory provided no procedure for review. 4. Review of the laboratory's reagent invoices revealed the BioSB Mohs Mouse/Rabbit PolyDetector HRP Brown Detection System was ordered on 10/24/2023 and shipped on 10/26/2023. No date of receipt was listed. 5. In an exit interview with the Office Manager on December 19, 2023, at approximately 3:00 PM, the above findings were confirmed.
D5423	ESTABLISHMENT AND VERIFICATION OF PERFORMANCE CFR(s): 493.1253(b)(2) Each laboratory that modifies an FDA-cleared or approved test system, or introduces a test system not subject to FDA clearance or approval (including methods developed in-house and standardized methods such as text book procedures), or uses a test system in which performance specifications are not provided by the manufacturer must, before reporting patient test results, establish for each test system the performance specifications for the following performance characteristics, as applicable: (2)(i) Accuracy. (2)(ii) Precision. (2)(iii) Analytical sensitivity. (2)(iv) Analytical specificity to include interfering substances. (2)(v) Reportable range of test results for the test system. (2)(vi) Reference intervals (normal values). (2)(vii) Any other performance characteristic required for test performance.

	This STANDARD is not met as evidenced by: Based on a tour of the laboratory, review of the laboratory's records, reagent invoices, Mohs logs, Food and Drug Administration's (FDA's) CLIA test categorization website, lack of documentation and interviews, the laboratory failed to validate the performance characteristics for the MART-1 Immunohistochemical (IHC) Stain utilizing the BioSB Mohs Mouse/Rabbit PolyDetector DAB HRP Brown Detection System while staining one (1) of 1 patient tissue specimens from October 26, 2023 until the date of the survey on December 18, 2023. The findings include: 1. During a tour of the laboratory on December 18, 2023 at approximately 9:00 AM, the surveyor noted a sheet of paper posted in the Mohs laboratory above the slide stainer with the title, "MART-1 ANTIBODY STAIN CHEAT SHEET". The Mohs Tech stated they used the "CHEAT SHEET" when performing MART-1 staining for suspected Melanoma specimens. The Mohs Tech provided the surveyor with a box labeled BioSB Mohs Mouse/Rabbit PolyDetector DAB HRP Brown Detection System (lot # 0307STNJ25 exp 7/2025) containing the BioSB TintoFast MART-1 MM Ab. 2. Review of the FDA's database revealed no listing or categorization for MART-1 Immunohistochemical (IHC) Staining utilizing the BioSB Mohs Mouse/Rabbit PolyDetector DAB HRP Brown Detection System. 3. The surveyor requested to review the validation of the performance specifications for the MART-1 Immunohistochemical (IHC) Staining utilizing the BioSB Mohs Mouse/Rabbit PolyDetector DAB HRP Brown Detection System. The laboratory provided no documentation to review. 4. Review of the laboratory's reagent invoices revealed the BioSB Mohs Mouse/Rabbit PolyDetector DAB HRP Brown Detection System was first ordered on 10/24/2023 and shipped on 10/26/2023. No date of receipt was listed. 5. Review of Mohs patient logs from October 26, 2023 until the date of the survey on December 18, 2023, revealed 1 patient specimen was stained on November 6, 2023 utilizing the MART-1 IHC BioSB Mohs Mouse/Rabbit PolyDetector DAB HRP Brown Detection System. 6. In an exit interview with the Office Manager on December 19, 2023, at approximately 3:00 PM, the above findings were confirmed.
D5601	HISTOPATHOLOGY CFR(s): 493.1273(a)(f) (a) As specified in 493.1256(e)(3), fluorescent and immunohistochemical stains must be checked for positive and negative reactivity each time of use. For all other differential or special stains, a control slide of known reactivity must be stained with each patient slide or group of patient slides. Reactions of the control slide with each special stain must be documented. (f) The laboratory must document all control procedures performed, as specified in this section. This STANDARD is not met as evidenced by: Based on a tour of the laboratory, review of the laboratory's quality control (QC) records, reagent invoices, Mohs logs, lack of documentation and interviews, the laboratory failed to document the positive and negative reactivity each day of use for one (1) of 1 patient tissue sample utilizing the MART-1 Immunohistochemical (IHC) stain from October 26, 2023 until the date of the survey on December 18, 2023. The findings include: 1. During a tour of the laboratory on December 18, 2023 at approximately 9:00 AM, the surveyor noted a sheet of paper posted in the Mohs laboratory above the slide stainer with the title, "MART-1 ANTIBODY STAIN CHEAT SHEET". The "CHEAT SHEET" listed the steps for performing the MART-

	1 antibody staining. The surveyor inquired of the Mohs Tech how the posted document was utilized. The Mohs Tech stated they used the "CHEAT SHEET" when performing MART-1 staining for suspected Melanoma specimens. The surveyor asked the Mohs Tech when they began using the MART-1 antibody stain. The Mohs Tech stated they recently began using the stain but wasn't sure of the date. 2. Review of the laboratory's reagent invoices revealed the MART-1 IHC stain utilizing the BioSB Mohs Mouse/Rabbit PolyDetector HRP Brown Detection System was first ordered on 10/24/2023 and shipped on 10/26/2023. There was no date of receipt listed. 3. Review of the laboratory's QC documentation revealed a lack of documentation of the MART-1 IHC stain positive and negative reactivity from October 26, 2023 until December 18, 2023. The surveyor requested to review the positive and negative stain reactivity for the MART-1 IHC stain. The laboratory provided no documentation to review. 4. Review of the Mohs logs from October 26, 2023 until December 18, 2023 revealed 1 patient tissue specimen was processed /stained on November 6, 2023 with the MART-1 IHC stain. 5. In an exit interview with the Office Manager on December 19, 2023, at approximately 3:00 PM , the above findings were confirmed.
D6076	LABORATORY DIRECTOR CFR(s): 493.1441 The laboratory must have a director who meets the qualification requirements of 493. 1443 of this subpart and provides overall management and direction in accordance with 493.1445 of this subpart. This CONDITION is not met as evidenced by: Based on a laboratory tour, review of the laboratory's policy and procedure manual, laboratory records, reagent invoices, quality control records, Mohs logs, lack of documentation, and interviews, the laboratory director failed to ensure: 1. the validation of the performance characteristics for MART-1 Immunohistochemical staining utilizing the BioSB Mohs Mouse/Rabbit PolyDetector HRP Brown Detection System prior to the testing of patients (see D6086). 2. the performance and documentation of positive and negative reactivity each day of use for MART-1 Immunohistochemical staining utilizing the BioSB Mohs Mouse/Rabbit PolyDetector HRP Brown Detection System (see D6093).
D6086	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(3)(ii) The laboratory director must ensure that verification procedures used are adequate to determine the accuracy, precision, and other pertinent performance characteristics of the method. This STANDARD is not met as evidenced by: Based on a tour of the laboratory, review of the laboratory's policies and procedures, method validation documents, reagent invoices, Food and Drug Administration's (FDA's) CLIA test categorization website, Mohs logs, lack of documentation, and interviews, the laboratory director failed to ensure the performance specifications for the high complexity MART-1 Immunohistochemical stain utilizing the BioSB Mohs

	Mouse/Rabbit PolyDetector HRP Brown Detection System were evaluated to determine accuracy and precision prior to processing/staining one patient from October 26, 2023 until the date of the survey on December 18, 2023 (see D5423).
D6093	LABORATORY DIRECTOR RESPONSIBILITIES CFR(s): 493.1445(e)(5) The laboratory director must ensure that the quality control programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur. This STANDARD is not met as evidenced by: Based on a tour of the laboratory, review of the laboratory's quality control (QC) records, reagent invoices, Mohs logs, lack of documentation, and interviews, the laboratory director failed to ensure the documentation of the positive and negative reactivity each day of use for the MART-1 Immunohistochemical stain for one (1) of 1 days of use from October 26, 2023 until the date of the survey on December 18, 2023 (see D5601).